

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-0149V

Filed: July 14, 2016

Unpublished

FRANCINE MACK,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

* Entitlement; Ruling on the Record;
* Decision Without a Hearing; Lack
* of Medical Opinion; Insufficient Proof;
* Influenza ("Flu") Vaccine; Shoulder
* Injury; Bursitis; Special Processing
* Unit ("SPU")
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James Mitchell, Richard Gage, PC, Cheyenne, WY for petitioner.

Sarah Duncan, U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

Dorsey, Chief Special Master:

On February 18, 2015, Francine Mack ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa–10, *et seq.*² (the "Vaccine Act" or "Program"), with two amended petitions filed thereafter. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

Petitioner alleges that she suffered injuries to her shoulders following influenza vaccinations on February 20, 2012, October 4, 2012, and December 5, 2013. Amended

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Petition at ¶¶ 2-8; Second Amended Petition at ¶¶ 3-6. For the reasons discussed herein, the undersigned must deny compensation.

I. Procedural History

Petitioner filed a petition for compensation under the Vaccine Act on February 18, 2015, alleging that she suffered a shoulder injury, including bursitis, as a result of an influenza vaccination she received on December 5, 2013. Petition at ¶¶ 2-4. Petitioner filed an affidavit with her petition, stating she received an influenza vaccination at the St. Joseph Medical Center, and that her “left shoulder started to hurt immediately after receipt of this vaccination.” Pet’r’s Affidavit, filed Feb. 18, 2015, at ¶¶ 4-5 (hereafter, “Pet’r’s Feb. 18 Aff.”). Petitioner also stated in her affidavit that she has “suffered pain and decreased range of motion as a result of this injury. This has effected [sic] [her] ability to perform tasks of daily living and has effected [sic] [her] ability to work.” *Id.* at ¶ 6. Petitioner filed medical records as Exhibits 1-8 and a statement of completion on March 2, 2015. ECF Nos. 6, 7.

The initial status conference was held on March 17, 2015, with the SPU staff attorney assigned to manage this case. During that call, petitioner’s counsel indicated that his client’s claim included additional vaccines and injuries not stated in the petition. He agreed to file an amended petition within 14 days, which clearly and accurately stated his client’s allegations. See Sched. Order, issued Mar. 18, 2015 (ECF No. 9), at 1. Respondent’s counsel requested additional medical records, including earlier pre-vaccination records, updated treatment records, any available vaccine administration records such as consent forms for each claimed vaccination, and a supplemental affidavit from petitioner. *Id.* Petitioner’s counsel stated he believed all available records had been submitted, but would consult with petitioner regarding the requested records. Petitioner’s counsel also agreed to obtain an affidavit from petitioner addressing, as necessary, her pre-vaccination medical history in the absence of additional records; the duration of her claimed injuries in the absence of supporting records; the non-existence of any relevant workers’ compensation claims; and any other gaps or discrepancies found in the record. *Id.* at 1-2.

Petitioner filed an amended petition on March 31, 2015, stating she received influenza vaccinations on February 20, 2012, and October 4, 2012, in the office of Fiertag and Ramos, P.A., in Baltimore, Maryland. Am. Petition at ¶ 2. According to the petition, petitioner sought treatment for neck pain and bilateral arm pain on or about June 22, 2012. *Id.* at ¶ 3. Petitioner received another influenza vaccine on December 5, 2013, and immediately felt pain in her shoulder. *Id.* at ¶¶ 4-5. Petitioner’s diagnoses include bursitis. *Id.* at ¶ 6. Petitioner alleges that her symptoms, which are chronic, were caused by the aforementioned influenza vaccinations. *Id.* at ¶ 8. Petitioner’s amended petition neither identified the arms in which she received each of the three vaccinations nor stated which vaccination caused which alleged injury. Petitioner filed a second affidavit and a statement of completion on April 16, 2015. In this affidavit,

petitioner stated that prior to the February 20, 2012 vaccination she was in good health and self-treated minor illnesses, “therefore no records exist for the time period of at least three years prior to [her] February 20, 2012 vaccination.” Pet’r’s Aff., filed Apr. 16, 2015 (ECF No. 11), at ¶ 2 (hereafter, “Pet’r’s Apr. 16 Aff.”). Petitioner attested that her shoulder pain, arm pain, and limitations in motion began following the first of the three vaccinations, but that she did not seek formal medical care because of a lack of medical insurance and financial constraints. *Id.* at ¶ 3.

A second status conference was held on April 30, 2015, with former Chief Special Master Vowell.³ During the conference, a number of evidentiary shortcomings in petitioner’s case were discussed. See Sched. Order, issued Oct. 5, 2015 (ECF No. 13), at 1. Petitioner requested and was granted an opportunity to obtain additional evidence, including medical records, insurance information, and affidavits from any witnesses. *Id.* On May 28, 2015, petitioner’s counsel was granted subpoena authority for records from petitioner’s former employer, St. Joseph’s Medical Center. ECF No. 16. Petitioner filed the records from St. Joseph’s Medical Center on September 11, 2015, as Exhibit 10. ECF No. 22.

A third status conference was held on October 2, 2015, with the assigned SPU staff attorney. During the conference, petitioner’s counsel stated that the records petitioner filed were not as illuminating as he had hoped; he also stated that no other medical records were available. See Sched. Order, issued Oct. 5, 2015 (ECF No. 25), at 1. Additionally, the SPU staff attorney and respondent’s counsel sought clarification regarding the injection site of each of the vaccines, as petitioner had not explicitly stated such in any of her filings, and it was not entirely clear from the medical records. *Id.* After further discussion, petitioner’s counsel agreed to file a second amended petition and another affidavit from petitioner to clarify this basic, yet important, issue. *Id.* at 1-2.

Petitioner filed a second amended petition on October 20, 2015, alleging she received influenza vaccinations on October 4, 2012 and December 5, 2013. Second Am. Petition at ¶ 2. Petitioner stated that the October 4, 2012 vaccination was in her right shoulder, and that she “recall[ed] the vaccination on December 5, 2013 as being in the left shoulder.” *Id.* at ¶ 3. Petitioner also stated that she reported a history of pain in her shoulders following the administration of the aforementioned vaccines to Orthopedic Specialist of Maryland. *Id.* at ¶ 4. Finally, she reiterated that she was diagnosed with bursitis, and that “her chronic symptoms were caused by her influenza vaccines administered October 4, 2012 and December 5, 2013.” *Id.* at ¶¶ 5-7. Petitioner made no mention of the February 20, 2012 vaccination. On October 26, 2015, petitioner filed another affidavit stating that she “believe[d] the flu vaccine on December 5, 2013 was administered in [her] left arm.” Pet’r’s Aff., filed Oct. 26, 2015 (ECF No. 31), at ¶ 4 (hereafter, “Pet’r’s Oct. 26 Aff.”). She “recognize[d] that the dates and area of

³ The case was reassigned to the undersigned on September 23, 2015, following the retirement of Chief Special Master Vowell. Notice of Reassignment, ECF No. 24.

administration of the vaccines ha[ve] been confusing” and that her statements “are in conflict with [her] previous affidavit.” *Id.* at ¶¶ 4, 6. Petitioner also indicated, contrary to previous assertions, that she had filed a Workers’ Compensation claim; however, she had not yet collected any award. *Id.* at ¶ 9. No documentation related to this claim has been filed.

On January 12, 2016, petitioner filed a motion for ruling on the record. Motion for Ruling on the Record, filed Jan. 12, 2016 (ECF No. 34). On January 14, 2016, respondent filed her Rule 4(c) Report and Motion to Dismiss, wherein she argued that petitioner’s claim should not be compensated and instead, should be dismissed. Respondent’s Rule 4(c) Report and Motion to Dismiss, filed Jan. 14, 2016 (ECF. No. 35), at 2.⁴

The matter is now ripe for adjudication. The undersigned issues this ruling on the record in response to petitioner’s motion for such ruling.

II. Medical History

Petitioner submitted limited pre-vaccination records. In her second affidavit, petitioner stated that the dearth of records was due to her “good health” prior to vaccination, and her ability to self-treat minor illnesses with her knowledge as a nurse. Pet’r’s Apr. 16 Aff. at ¶ 2. Consequently, “no records exist for the time period of at least three years prior to [her] February 20, 2012 vaccination.” *Id.* The following is based on the few records filed by petitioner.

On February 20, 2012, petitioner received a flu vaccination in her right deltoid at Feirtag and Ramos, P.A., in Baltimore, Maryland. Exhibit 1 at 5.⁵

On June 2, 2012, petitioner presented to her primary care physician, Dr. Manuel Ramos, complaining of “pain on side” and “nodule on l[eft] thumb.” Exhibit 1 at 12. On June 22, 2012, petitioner underwent an MRI of the thoracic and cervical spine. Exhibit 3 at 5-6. The MRI report noted a history of “Neck pain and bilateral arm pain, neck stiffness, mid-back pain symptoms for two months.” *Id.* at 5. The MRI revealed mild degenerative changes in the upper-to-mid spine without evidence of canal or foraminal stenosis, but mild-to-moderate central canal stenosis and bilateral foraminal narrowing in the cervical spine. *Id.* at 6.

⁴ Respondent filed a status report on Feb. 3, 2016 advising the undersigned that she intended her Rule 4(c) Report and Motion to Dismiss to serve as her response to Petitioner’s Motion for Ruling on the Record. Status Rep., filed Feb. 3, 2016 (ECF No. 36).

⁵ There are contradictory notations in the record of this case regarding the date of this vaccination. For the reasons discussed in footnote 11, below, the undersigned has concluded that the preponderance of the evidence supports February 20, 2012, as the date of vaccination.

According to petitioner's Employee Medical Activity History, she received another flu vaccination on October 4, 2012, which was administered by "LH" in her "RD" [right deltoid]. Exhibit 8 at 1. Petitioner provided no additional medical records relating to this vaccination, but attested that she received this vaccination in her right arm. Pet'r's Oct. 26 Aff. at ¶ 3.

On November 8, 2013, petitioner underwent a right shoulder MRI. Exhibit 3 at 8. The MRI report noted a history of "Right shoulder and right arm pain. Limited range of motion." *Id.* This MRI, which was one year and nine months after the February 20, 2012 vaccination, was requested by Dr. Ramos, possibly during a visit reflected in an undated record noting that an MRI was planned for petitioner's right shoulder. *Id.*⁶ The MRI revealed moderate tendinosis of the subscapularis and supraspinatus tendons, mild subacromial subdeltoid bursitis and "tiny subcoracoid bursa," an intact rotator cuff, mild AC joint osteoarthritis, and possible mild fraying of the superior labrum. *Id.*

According to petitioner's Employee Medical Activity History, she received another flu vaccination on December 5, 2013. Exhibit 8 at 4. Petitioner provided no additional medical records relating to this vaccination; however, petitioner stated in an affidavit that she believed it "was administered in [her] left arm." Pet'r's Oct. 26 Aff. at ¶ 4.⁷

On January 11, 2014, petitioner again saw Dr. Ramos complaining of pain in her left arm following a flu shot, and a problem with her right arm.⁸ Exhibit 1 at 26. An MRI of petitioner's left shoulder followed on January 13, 2014. Exhibit 3 at 10. The MRI report indicated petitioner had "[l]eft shoulder pain and upper extremity weakness beginning several months prior to exam." *Id.* The MRI showed no evidence of rotator cuff tear, very mild arthritic changes of the AC joint space, and a mild degree of subacromial and subdeltoid bursal fluid, which "may be related to mild degree of bursitis." *Id.*⁹

⁶ This undated record from Dr. Ramos notes right shoulder pain after injection. Exhibit 1 at 17. However, since it is undated, and there is no context for the notation (the record does not indicate the type of injection or when it was administered), it is of little probative value.

⁷ An undated "Influenza Vaccine (Flu Shot) Consent Form" reflects that petitioner received a vaccination in her "L. Deltoid", indicating petitioner was injected in her left deltoid. Exhibit 10 at 10. Petitioner also wrote on this form that she had had a bad reaction to a previous flu shot, with additional hand-written notion of "sore muscle" and "my previous flu shot left my arm swollen tender + sore[.] MRI reveals a frayed muscle that has bursitis + tendinitis." *Id.* However, since this form is undated, it is of little probative value.

⁸ Dr. Ramos notes "Flu shot (L) arm now pain" and "(R) arm gave out." Exhibit 1 at 26.

⁹ On January 13, 2014, petitioner also had an MRI of her brain, citing a history of headaches and bilateral extremity weakness. Exhibit 3 at 9. The MRI revealed a possible small micro adenoma, but otherwise was a normal exam. *Id.*

On March 25, 2014, petitioner transitioned from the care of Dr. Ramos to Dr. Allan Lanzo of the Orthopaedic Specialists of Maryland. Exhibit 5 at 1. Dr. Lanzo reported that the reason for petitioner's visit was sudden shoulder pain that manifested after a flu vaccination and had persisted in an intermittent pattern for 9 months. *Id.* Petitioner reported pain "in the left shoulder, right shoulder, left side of the neck and right side of the neck." *Id.* In his summary of the encounter, Dr. Lanzo wrote:

The patient comes in today with complaints of bilateral shoulder pain. She has interesting history where she felt that her right shoulder pain began after a flu vaccine a year ago and her left shoulder pain began nine months later after a second flu vaccine in that arm. She reports that both shoulders are painful. She notes some occasional numbness or tingling although that is not a predominant complaint. She has some aching at rest, but most of her pain is in the shoulders and radiating down into the arms and that is usually post activity.

Id. at 3. Dr. Lanzo's examination revealed petitioner had "some mild impingement signs, but nothing dramatic." *Id.* He also expressed skepticism as to a causal link between petitioner's vaccinations and her shoulder pain, noting that "[i]t is a little bit unclear as to the mechanism of the connection between the flu vaccine and her ongoing shoulder difficulties." *Id.*

Petitioner saw a neurologist, Dr. James Wolf, on April 4, 2014, complaining of right upper arm pain. Exhibit 6 at 1. Dr. Wolf stated petitioner did not have "any new abnormalities on her exam" and referred her for an electrodiagnostic study and ordered another MRI scan. *Id.*

On April 15, 2014, petitioner underwent an electromyography and nerve conduction study on both arms and her left leg. Exhibit 7 at 1. One of the reasons for the study was to understand petitioner's symptoms following "a flu shot." *Id.* A handwritten note states "pain of upper arms since flu shots x2 years." *Id.* at 2. The study revealed no significant abnormalities, but did indicate a "minimal change of left median" in the arm. *Id.* at 1.

III. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if she has received a vaccine covered by the Program and "sustained, or had significantly aggravated, any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the "Table"). § 11(c)(1)(A) and (C)(i). The most recent version of the Table, which can be found at 42

C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination.¹⁰ § 14(a). If the petitioner establishes that she suffered such a “Table Injury,” causation is presumed. *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1146–47 (Fed.Cir.1992).

If, however, the petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, the petitioner must prove that the claimed vaccine caused the alleged injury to receive compensation. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner is said to assert a “non-Table” or “off-Table” claim, and must prove her claim by preponderant evidence. § 13(a)(1)(A). A special master is prohibited from making “such a finding “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” § 13(a)(1). This standard is “one of . . . simple preponderance, or ‘more probable than not’ causation.” *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec’y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioner must “prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Federal Circuit has indicated that petitioner “must show ‘a medical theory causally connecting the vaccination and the injury’” to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant*, 956 F.2d at 1148). Additionally, “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” *Id.* The Federal Circuit subsequently restated these requirements in its *Althen* decision. *Althen* requires a petitioner

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

418 F.3d at 1278. All three prongs of *Althen* must be satisfied. *Id.*

¹⁰ The Vaccine Act authorizes the Secretary of the Department of Health and Human Services to “promulgate regulations” to periodically modify the Vaccine Injury Table. § 14(c). The updates are contained in the Code of Federal Regulations (C.F.R.), as cited above.

Section 11(c)(1) also contains requirements concerning the type of vaccination received and the geographic location where it was administered, the duration or significance of the injury, and the lack of any other award or settlement. See § 11(c)(1)(A),(B),(D) and (E). With regard to duration, whether a Table or non-Table claim, the petitioner must establish she

(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

§ 11(c)(1)(D).

IV. Analysis

Petitioner alleges in three petitions that influenza vaccinations she received on February 20, 2012, October 4, 2012, and December 5, 2013, caused her to suffer painful injuries to her shoulders. Pet. at ¶¶ 2-6; Am. Petition at ¶¶ 2-8; Second Am. Petition at ¶¶ 3-7. Although not explicitly stated, petitioner is essentially claiming what is known as shoulder injury related to vaccine administration or “SIRVA.”

Respondent opposes compensation in this case, arguing that petitioner has not produced sufficient evidence to support any of her claims. *See* Respondent’s Rule 4(c) Report and Motion to Dismiss, filed Jan. 14, 2016.

After a thorough review of the record, the undersigned finds petitioner has provided evidence sufficient to establish receipt of the three vaccinations, but, as discussed in greater detail below, has not established that the vaccinations actually caused the alleged injuries. Specifically, petitioner has failed to satisfy all three prongs of *Althen* for each claimed injury—she has not provided sufficient evidence to establish a medical theory of causation; she has not set forth a logical sequence of cause and effect showing the claimed vaccinations caused any of her alleged injuries; and she has not established a proximal temporal relationship between two of the vaccinations and the corresponding alleged injuries. Each vaccination is addressed in turn.

1. Petitioner’s February 20, 2012 Vaccination

The first vaccination to allegedly injure petitioner was an influenza vaccine given into her right arm on February 20, 2012.¹¹ Am. Petition at ¶ 2; Exhibit 1 at 5. Petitioner,

¹¹ The medical records provide contradictory dates for the February vaccination. The “Vaccine Administration, Assessment, and Consent Form” reflects that petitioner signed the form on February 15, 2012, and indicates that it was administered on that date to her right deltoid. Exhibit 1 at 5. Petitioner’s

however, made no mention of this vaccination in her Second Amended Petition, so it is unclear whether she has abandoned this allegation. Out of an abundance of caution, the undersigned assumes petitioner did not abandon the claim and considers it herein.

a. Alleged Injury

Petitioner claims that her chronic symptoms, including shoulder pain, arm pain, limitations in motion, and bursitis, were caused in part by the February 20, 2012 influenza vaccination. Am. Petition at ¶¶ 2-8; Pet'r's Apr. 16 Aff. at ¶ 3. In support of her claim, petitioner refers to the records of her treatment for neck pain and bilateral arm pain on June 22, 2012. Am. Petition at ¶ 3; See Exhibit 3 at 5-6. However, the record does not show the neck and bilateral arm pain was attributed or associated with petitioner's February 20, 2012 vaccination. Moreover, petitioner attested that she did not seek any formal treatment for her vaccine-related injuries because she lacked medical insurance and had financial constraints. Pet'r's Apr. 16 Aff. at ¶ 3.

b. A Medical Theory Causally Connecting the Vaccination and Injury

To satisfy the first *Althen* prong, the petitioner must show that the vaccination in question can cause the injury alleged. See *Pafford v. Sec'y of Health & Human Servs.*, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). The petitioner must offer a medical theory which is reputable and reliable. See, e.g., *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (reputable); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (reliable). The petitioner must prove this prong by preponderant evidence. *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

Here, petitioner has not filed the report of a medical expert or offered any medical theory showing that the February 20, 2012 influenza vaccination could have caused or aggravated her alleged injuries. Further, there is nothing in the medical records from a physician or other medical professional providing such a theory.¹² Petitioner, therefore, has failed to satisfy the first *Althen* prong.

c. A Logical Sequence of Cause and Effect

amended petition, second affidavit, and Employee Medical Activity History reflect the vaccine was received on February 20, 2012. Am. Petition at ¶ 2; Pet'r's Apr. 16 Aff. At ¶ 2; Exhibit 8 at 1. Based on the record as a whole, the undersigned finds that, by a preponderance of evidence, petitioner's vaccine was administered on February 20, 2012.

¹² Petitioner was afforded ample opportunity to secure a medical opinion setting forth a causal theory. Petitioner's motion for a ruling on the record, which was filed voluntarily, unequivocally states that petitioner "submitted all the evidence that [she] believes the Chief Special Master needs to issue a ruling in this case." Motion for Ruling on the Record, filed Jan. 12, 2016 (ECF No. 34). Thus, petitioner cannot claim she was deprived of the opportunity to submit evidence in support of this prong.

To satisfy the second *Althen* prong, the petitioner must prove that the vaccine she received did cause her injury. *Pafford*, 2004 WL 1717359, at *4. The petitioner must provide preponderant evidence of causation. See *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). In determining whether the petitioner has met this burden of proof under this prong, the special master must consider the opinions of any treating physicians who conclude that the claimed vaccine was the cause of the alleged injury. *Id.* Any diagnosis, conclusion, or medical judgment contained in the record must be considered when determining if compensation is appropriate. § 13(b)(1).

Here, petitioner has not furnished evidence that the February 20, 2012 vaccination caused or contributed to her reported injuries. None of petitioner’s treating medical professionals attributed her condition to the vaccination she received. For example, when petitioner first sought treatment for neck pain and bilateral arm pain in June of 2012, there was no mention of an influenza vaccination. See Exhibits 1 at 12, 14; 3 at 6. Further, petitioner did not submit a medical opinion supporting causation from any treating physician or other qualified expert.

The medical records petitioner provided attributed her symptoms to other causes, including degenerative changes in petitioner’s spine. See, e.g., Exhibit 3 at 6 (indicating her neck and bilateral arm pain was due to “Mild degenerative changes in the upper-to-mid thoracic and cervical spine”).

For all these reason, petitioner has not established a logical sequence of cause and effect showing that the February 20, 2012 vaccination caused or aggravated her alleged injuries. She has failed to satisfy the second *Althen* prong.

d. A Proximate Temporal Relationship between Vaccination and Injury

The third *Althen* prong requires the petitioner to provide preponderant evidence that the first symptom or onset of the injury “occurred within a timeframe for which . . . it is medically acceptable to infer causation-in-fact.” *de Bazan v. Sec’y of Health and Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The petitioner must show that the injury did not occur too soon or too long after vaccination. *Id.*

Here, petitioner claims that her “shoulder and arm pain and limitations in motion began following [her] vaccine on February 20, 2012,” and that she did not seek any care due to a lack of medical insurance and financial constraints. Pet’r’s Apr. 16 Aff. at ¶ 3. However, contemporaneous medical evidence indicates petitioner’s symptoms first occurred in April 2012. Exhibit 3 at 5 (a June 2012 record noting that petitioner had experienced symptoms including neck pain and bilateral arm pain, neck stiffness, mid-back pain “for two months”). This medical evidence outweighs petitioner’s unsupported

assertions. Indeed, the undersigned may not make a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion. § 13(a). Therefore, when viewing the record as a whole, the undersigned finds that the earliest onset of petitioner's injuries was April 2012, at least six weeks after her February 20, 2012 vaccination.

The Secretary has proposed amending the Vaccine Injury Table to add the injury of SIRVA. See Revisions to the Vaccine Injury Table, 80 Fed. Reg. at 45,132.¹³ According to the proposal, the timeframe for onset is less than or equal to 48 hours. *Id.* at 45,136. In petitioner's case, 48 hours after vaccination would be February 22, 2012. The undersigned recognizes that the proposed time frame does not mean that a petitioner cannot not obtain compensation for a claim involving a later onset (even one that is substantially later), but the petitioner must provide evidence establishing that the later onset is medically acceptable to infer causation.

In petitioner's case, even based on the earliest date of onset (April 1, 2012), the time between vaccination and onset is at least 42 days (21 times the length of time set forth in the proposed table change), and petitioner has provided no evidence that an onset occurring at that time is medically acceptable to infer causation. Petitioner has failed to provide evidence of a proximate temporal relationship between vaccination and injury, and thus, has failed to fulfill the third *Althen* prong.

2. Petitioner's October 4, 2012 Vaccination

The second vaccination to allegedly injure petitioner was an influenza vaccine given into her right shoulder on October 4, 2012. Second Am. Petition at ¶ 3; Exhibit 8 at 1; Pet'r's Oct. 26 Aff at ¶ 3.¹⁴

a. Alleged Injury

Petitioner claims that her chronic symptoms, including shoulder pain and bursitis, were caused in part by the October 4, 2012 influenza vaccination. Second Am. Petition at ¶¶ 3-7. While petitioner attests that she reported pain in her arm and shoulders related to the flu vaccine (Pet'r's Oct. 26 Aff at ¶ 5), the record shows no evidence of petitioner reporting any shoulder pain until November 2013, more than a year after the

¹³ Available at <https://federalregister.gov/a/2015-17503>.

¹⁴ Respondent argues that petitioner has not provided adequate proof of her October 4, 2012 influenza vaccination. Resp't's Rule 4(c) Report and Motion to Dismiss, filed Jan. 14, 2016, at 13. However, based on petitioner's affidavit and employment records, the undersigned finds that she has shown, by a preponderance of the evidence, that she received the vaccination in her right shoulder on October 4, 2012. Second Am. Petition at ¶ 3; Exhibit 8 at 1; Pet'r's Oct. 26 Aff at ¶ 3.

October 4, 2012 vaccination (Exhibit 3 at 8; see *also* Exhibit 1 at 17¹⁵). On November 8, 2013, petitioner underwent an MRI of her right shoulder for a history of “Right shoulder and right arm pain. Limited range of motion.” Exhibit 3 at 8. The MRI showed moderate tendinosis of the subscapularis tendon and supraspinatus tendon; mild subacromial subdeltoid bursitis and tiny subcoracoid bursa; mild AC joint osteoarthritis; and possible mild fraying of the superior labrum. *Id.* However, the record does not show that the right shoulder and right arm pain were attributed or associated with petitioner’s October 4, 2012 vaccination.

b. A Medical Theory Causally Connecting the Vaccination and Injury

To satisfy the first *Althen* prong, the petitioner must show that the vaccination in question can cause the injury alleged. See *Pafford*, 2004 WL 1717359, at *4. The petitioner must offer a medical theory which is reputable and reliable. See, e.g., *Pafford*, 451 F.3d at 1355 (reputable); *Moberly*, 592 F.3d at 1324 (reliable). The petitioner must prove this prong by preponderant evidence. *Broekelschen*, 618 F.3d at 1350.

Here, petitioner has not filed the report of a medical expert or offered any medical theory showing that the October 4, 2012 influenza vaccination could have caused or aggravated her alleged injuries. Further, there is nothing in the medical records from a physician or other medical professional providing such a theory. Petitioner, therefore, has failed to satisfy the first *Althen* prong.

c. A Logical Sequence of Cause and Effect

To satisfy the second *Althen* prong, the petitioner must prove that the vaccine she received did cause her injury. *Pafford*, 2004 WL 1717359, at *4. The petitioner must provide preponderant evidence of causation. See *Capizzano*, 440 F.3d at 1326. In determining whether the petitioner has met this burden of proof under this prong, the special master must consider the opinions of any treating physicians who conclude that the claimed vaccine was the cause of the alleged injury. *Id.* Any diagnosis, conclusion, or medical judgment contained in the record shall be considered when determining if compensation is appropriate. § 13(b)(1).

Here, petitioner has not provided evidence that the October 4, 2012 vaccination caused or contributed to her injuries. None of petitioner’s treating medical professionals attributed her condition to the vaccination she received. For example, when petitioner first sought treatment for right shoulder pain, right arm pain, and limited range of motion in November of 2013, there was no mention of the influenza vaccination. See Exhibits 1

¹⁵ This undated record from Dr. Ramos reflects a complaint of right shoulder pain after injection. Because the record notes that an MRI was planned for petitioner’s right shoulder, it is possible that this visit occurred contemporaneously with the MRI. Even if the visit occurred in October 2013, it would have taken place a year after petitioner received her October 4, 2012 vaccination.

at 16; 3 at 8. Further, it was not until March of 2014 when petitioner first mentioned any alleged relationship between her October 2012 influenza vaccination and her injury. Exhibit 5 at 1. Although petitioner was diagnosed with mild bursitis, which can be caused by an errant vaccination, there is no indication in petitioner's record of when it was onset or any statement, notation, or opinion from a medical professional indicating her vaccination was the cause.

Moreover, petitioner did not submit a medical opinion supporting causation from any treating physician or other qualified expert. Instead, petitioner's medical records reflect a treating physician questioning whether her injuries were caused by her flu vaccination. On March 25, 2014, petitioner saw Dr. Allan Lanzo, an orthopedic specialist, complaining of right shoulder pain that "she felt...began after a flu vaccine a year ago...." Exhibit 5 at 3. Dr. Lanzo opined that "[i]t is a little bit unclear as to the mechanism of the connection between the flu vaccine and her ongoing shoulder difficulties." *Id.*

For all these reason, petitioner has not established a logical sequence of cause and effect showing that the October 4, 2012 vaccination caused or aggravated her alleged injuries. She has failed to satisfy the second *Althen* prong.

d. A Proximate Temporal Relationship between Vaccination and Injury

The third *Althen* prong requires the petitioner to provide preponderant evidence that the first symptom or onset of the injury "occurred within a timeframe for which . . . it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352. The petitioner must show that the injury did not occur too soon or too long after vaccination. *Id.*

Petitioner's various petitions and affidavits have inconsistently reported when the onset of her injury occurred. In her initial petition, petitioner claimed that her "chronic symptoms were caused by her influenza vaccination administered on December 5, 2013." Petition at ¶ 5. In petitioner's Amended Petition, she claimed her "shoulder began to hurt immediately after receipt of [the December 5, 2013] influenza vaccination." Am. Petition at ¶ 5. In her affidavit filed in support of her Amended Petition, petitioner claimed that her "shoulder and arm pain and limitations in motion began following [her] vaccine on February 20, 2012." Pet'r's Apr. 16 Aff. at ¶ 3. In petitioner's Second Amended Petition, petitioner claimed "a history of pain in her shoulders following administration of the [October 4, 2012 and December 5, 2013] vaccines." Second Am. Petition at ¶ 4.

The medical records also contain inconsistent reporting as to when petitioner first experienced symptoms of the injuries she relates to her October 4, 2012 vaccination. According to petitioner's medical records, she first complained of right shoulder and arm

pain and limited range of motion in November of 2013, which is 13 months after the October 4, 2012 vaccination. Exhibits 1 at 16; 3 at 8. There is no reference or other indication that petitioner, or any medical professional, attributed the problems she reported at that visit to her vaccination.¹⁶ The first instance where petitioner attributed any injury to her vaccination was during a March 25, 2014 visit to an orthopedic specialist—but even then she provided conflicting reports as to the onset of her alleged injuries: she reported the “onset of shoulder pain [was] sudden (after a flu vaccine) and ha[d] been occurring in an intermittent pattern for 9 months”; however, she also “felt that her right shoulder pain began after a flu vaccine a year ago....” Exhibits 5 at 1, 3. If petitioner’s assertions are accurate, her right shoulder pain would have first occurred either in June or April of 2013—approximately eight or six months, respectively, after petitioner’s October 2012 vaccine.

The undersigned may not make a finding based on the claims of the petitioner alone, unsubstantiated by medical records or by medical opinion. § 13(a). Therefore, when viewing the record as a whole, the undersigned finds that the earliest onset of petitioner’s injuries was April of 2013, at least six months after the October 4, 2012 vaccination.

As discussed above, the Secretary’s proposal to add the injury of SIRVA to the Vaccine Injury Table includes a time frame for onset of less than or equal to 48 hours. In petitioner’s case, 48 hours after vaccination would be October 6, 2012. The undersigned recognizes that the proposed time frame does not mean that a petitioner cannot not obtain compensation for a claim involving a later onset (even one that is substantially later), but the petitioner must provide evidence establishing that the later onset is medically acceptable to infer causation.

Here, even assuming the earliest date of onset (April 2013), the time between vaccination and onset is approximately six months, and petitioner has provided no evidence that an onset occurring at that time is medically acceptable to infer causation. Petitioner has failed to provide evidence of a proximate temporal relationship between vaccination and injury, and thus, has failed to fulfill the third Althen prong.¹⁷

3. Petitioner’s December 5, 2013 Vaccination

¹⁶ As previously discussed, an undated record from Dr. Ramos (Exhibit 1 at 17) notes right shoulder pain after injection. The undated record, however, provides no context for the notation (the record does not indicate the type of injection or when it was administered), and, most importantly, does not establish when petitioner first experienced the alleged symptoms. The record is therefore given little weight.

¹⁷ Petitioner also failed to demonstrate that she “suffered the residual effects of such ... injury, or condition for more than 6 months after administration of the vaccine.” See § 11(c)(1)(D).

The third vaccination to allegedly injure petitioner was an influenza vaccine given into her left shoulder on December 5, 2013. Second Am. Petition at ¶¶ 2-3, 7; Exhibit 8 at 4; Pet'r's Oct. 26 Aff. at ¶ 4.¹⁸

a. Alleged Injury

Petitioner claims that her chronic symptoms, including shoulder pain and bursitis, were caused in part by the December 5, 2013 influenza vaccination. Second Am. Petition at ¶¶ 3- 7. While petitioner attests that she reported pain in her arm and shoulders related to the flu vaccine (Pet'r's Oct. 26 Aff. at ¶ 5), the record shows no evidence of petitioner complaining of any shoulder pain until January 11, 2014, when she reported pain in her left arm following a flu shot (Exhibit 1 at 26). A subsequent MRI of petitioner's left shoulder on January 13, 2014, showed mild degree of subacromial and subdeltoid bursal fluid and a mild degree of bursitis. Exhibits 1 at 19; 3 at 10. However, the record does not indicate the left shoulder pain was attributed or associated with petitioner's December 5, 2013 vaccination.

b. A Medical Theory Causally Connecting the Vaccination and Injury

To satisfy the first *Althen* prong, the petitioner must show that the vaccination in question can cause the injury alleged. See *Pafford*, 2004 WL 1717359, at *4. The petitioner must offer a medical theory which is reputable and reliable. See, e.g., *Pafford*, 451 F.3d at 1355 (reputable); *Moberly*, 592 F.3d at 1324 (reliable). The petitioner must prove this prong by preponderant evidence. *Broekelschen*, 618 F.3d at 1350 (Fed. Cir. 2010).

Here, petitioner has not filed the report of a medical expert or offered any medical theory showing that the December 5, 2013 influenza vaccination could have caused or aggravated her alleged injuries. Further, there is nothing in the medical records from a physician or other medical professional providing such a theory. Petitioner, therefore, has failed to satisfy the first *Althen* prong.

c. A Logical Sequence of Cause and Effect

To satisfy the second *Althen* prong, the petitioner must prove that the vaccine she received caused her injury. *Pafford*, 2004 WL 1717359, at *4. The petitioner must provide preponderant evidence of causation. See *Capizzano*, 440 F.3d at 1326. In determining whether the petitioner has met this burden of proof under this prong, the special master must consider the opinions of any treating physicians who conclude that

¹⁸ Respondent argues that petitioner has not provided adequate proof of her December 5, 2013 influenza vaccination. Resp't's Rule 4(c) Report and Motion to Dismiss, filed Jan. 14, 2016, at 13. However, based on petitioner's affidavit and employment records, the undersigned finds that she has shown, by a preponderance of the evidence, that she received the vaccination in her left shoulder on December 5, 2013. Second Am. Petition at ¶¶ 2-3, 7; Exhibit 8 at 4; Pet'r's Oct. 26 Aff. at ¶ 4.

the claimed vaccine was the cause of the alleged injury. *Id.* Any diagnosis, conclusion, or medical judgment contained in the record shall be considered when determining if compensation is appropriate. § 13(b)(1).

Here, petitioner has not provided evidence that the December 5, 2013 vaccination caused or contributed to her injuries. None of petitioner's treating medical professionals attributed her condition to the vaccination she received. For example, while petitioner apparently reported left shoulder pain following a flu vaccination (Pet'r's Oct. 26 Aff. at ¶ 5), the medical records indicate she did not seek any treatment for shoulder pain until January of 2014. See Exhibits 1 at 26; 3 at 10. Further, on January 13, 2014 petitioner claimed that the shoulder pain began "several months prior to exam" (Exhibit 3 at 10), and later on March 25, 2014 claimed that she had been experiencing left shoulder pain for approximately 3 months (Exhibit 5 at 3). Although petitioner was diagnosed with mild bursitis and showed signs of mild impingement, there is no indication in the record that the injuries were attributed to the December 5, 2013 vaccination. Exhibits 1 at 26; 3 at 10; 5 at 3.

Moreover, petitioner did not submit a medical opinion supporting causation from the treating physician or another expert, but did submit medical records indicating a treating physician questioned whether her injuries could have been caused by the flu vaccination. On March 25, 2014, Dr. Allan Lanzo, noted that "[i]t is a little bit unclear as to the mechanism of the connection between the flu vaccine and her ongoing shoulder difficulties." Exhibit 5 at 3.

For all these reason, petitioner has not established a logical sequence of cause and effect showing that the December 5, 2013 vaccination caused or aggravated her alleged injuries. She has failed to satisfy the second *Althen* prong.

d. A Proximate Temporal Relationship between Vaccination and Injury

The third *Althen* prong requires the petitioner to provide preponderant evidence that the first symptom or onset of the injury "occurred within a timeframe for which . . . it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352. The petitioner must show that the injury did not occur too soon or too long after vaccination. *Id.*

Here, petitioner statements regarding the onset of her injuries have been inconsistent. In her first petition, she claimed her shoulder began to hurt immediately after receipt of [the December 5, 2013] influenza vaccination." Petition at ¶ 2-3; Pet'r's Feb. 18 Aff. at ¶ 5. However, petitioner's Second Amended Petition claims that she experienced pain in her shoulders following the administration of both the October 4, 2012 and December 5, 2013 vaccinations. Second Am. Petition at ¶¶ 3-4. The medical records provide some clarity. On January 11, 2014 petitioner presented to Dr. Ramos,

who indicated “Flu shot [left] arm now pain[.]” Exhibit 1 at 26. Further, Dr. Ramos ordered a left shoulder MRI for petitioner based on a history of “Left shoulder pain and upper extremity weakness beginning several months prior to exam[.]” Exhibit 3 at 10. If this is accurate, petitioner’s left shoulder pain would have first occurred either in October or November of 2013, before petitioner even received the December 5, 2013 vaccination.

Despite petitioner’s inconsistent statements, there is preponderant evidence that petitioner’s left shoulder pain occurred immediately after her December 5, 2013 vaccination. Specifically, the undersigned credits the above-described January 11, 2014 medical record and petitioner’s February 18, 2015 affidavit. As already discussed, the proposal to add the injury of SIRVA to the Vaccine Injury Table includes a time frame for onset of less than or equal to 48 hours. Here, the onset of petitioner’s claimed injuries to her left shoulder was immediate. Petitioner has therefore established a proximate temporal relationship between vaccination and injury, and thus, fulfilled the requirements of the third *Althen* prong. However, establishing temporal association is not sufficient to establish causation-in-fact. *Grant*, 956 F.2d at 1148.

e. Six month requirement

Ignoring all other defects, petitioner still would not be entitled to compensation under the Vaccine Program based on the December 5, 2013 vaccination because she has not demonstrated that she “suffered the residual effects of such ... injury, or condition for more than 6 months after administration of the vaccine.” § 11(c)(1)(D). Petitioner only provided medical records through April 15, 2015 (Exhibit 7 at 1), despite ample opportunity to supplement the record. Petitioner asserts that she has suffered the residual effects of her alleged vaccine-related injuries for more than six months, and that her symptoms continue. Second Am. Petition at ¶ 8; Pet’r’s Oct. 26 Aff. at ¶ 7. However, there are no medical records to support this statement, and the undersigned “may not make such a finding based on the claims of a petitioner alone.” § 13(a)(1).

Therefore, in addition to not meeting the first two *Althen* prongs, petitioner has not demonstrated that she has suffered the residual effects of her alleged injuries for more than six months.

V. Conclusion

For the reasons set forth above, petitioner has failed to establish entitlement to compensation under the Vaccine Act. This case is dismissed for insufficient proof. The Clerk of the Court is directed to enter judgment in accordance with this decision.¹⁹

¹⁹ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master